REMARKS

Claims 1-13 and 17 were canceled earlier due to restrictions imposed by the Examiner and required to be withdrawn from consideration. Claim 24 is being canceled due to restriction imposed by the Examiner and required to be withdrawn from consideration. Independent claims 14 and 31 are amended to specify that the outer layer is embossed and that the secondary drug containing reservoir is in a layer, as well that the backing is used with a device having a primary drug containing reservoir. Support for the amendment can be found, for example, in the drawings, and paragraphs 0030 and 0050 in the specification. Claims 20 and 31 are also amended to correct minor clerical errors. No new matter is added in the amendment or the new claims. Thus, claims 14-16, 18-23, and 25-31 are pending.

Telephone Interview

Applicant notes with appreciation the courtesy extended to Applicant's attorney, Philip Yip, in the telephone interview of October 11, 2006. During the telephone interview, the claim objection on claim 20 and the Examiner's statement on omitted cooperative relationship were discussed. Applicant's attorney suggested correcting the spelling in claim 20 and adding a word on layer relating to the secondary drug reservoir. Further, points of the invention related to embossing were discussed. Applicant's attorney suggested adding a limitation on that the outer layer is embossed. Also, the cited reference Burkoth et al. US5785991 was discussed. Applicant's attorney pointed out that in US5785991 the porous layer is skin contacting and therefore is not an outer layer of a backing construction. No agreement on claim allowance was arrived at.

Claim Objection

The Examiner objected to claim 20 due to a misspelling. The misspelling has been corrected. Withdrawal of the objection is requested.

35USC §112 second paragraph rejection

Claims 14-16, 18-23, and 25-31 were rejected as being incomplete for omitting essential structural cooperative relationship of elements under 35USC §112 second paragraph. Applicant respectfully traverses the rejection. The Examiner wanted to know whether the secondary drug reservoir in the tie layer is a layer. Applicant submits that because prior art reference do not teach or suggest a multilaminate backing with a secondary drug reservoir in a tie layer and that a person skilled in the art reading the present specification will know that the secondary drug reservoir can take many different forms and positions, Applicant should not be required to put in every detail in the broad claims. If Applicant were required to put in such details in an application, not to overcome prior art but to be specific, Applicant would need to file many more divisional and continuation applications so as to cover other embodiments. This would impose severe labor and financial burden on Applicant. Furthermore, there are many variations that a person skilled in the art can made based on the disclosure of the present invention and it would be impossible to elaborate on all such details in an application. Nevertheless, in order to facilitate the allowance of claims certain embodiments of the present invention, Applicant amends the broad claims to include language that the secondary drug reservoir in the tile layer is a secondary drug reservoir layer. Withdrawal of the rejection is respectfully requested.

35USC §102 rejection

Claims 14, 15, 19, and 25 were rejected under 35USC §102(b) as being anticipated by Burkoth et al. US5785991. Applicant respectfully traverses the rejection. The Examiner asserted that Burkoth et al. have a rate controlling membrane as a base layer for controlling the release rate of the enhancer from zone 12 to the skin 17. Applicant disagrees. The Examiner admits that the Burkoth et al. device has layers 12, 13, 14 in sequence. Applicant submits that the rate controlling membrane of Burkoth et al. (i.e., layer 13) is between zone 12 and zone 14 (drug layer facing the skin) and therefore is not a top layer, and definitely not a BASE LAYER.

The Examiner further asserted that in the embodiment of Burkoth et al. "Fig. 2 [drug layer] can be fully enclosed in a permeable or microporous skin-contacting membrane (outer layer) [col. 8, lines 14-19]". However, Applicant respectfully points out that even the Examiner admitted in the office action that the microporous layer of Burkoth et al. is skin contacting. If it is skin contacting, it cannot be a backing. It is noted that in the present invention the backing construction is for use with a primary drug containing reservoir in a device for delivery of drug to the skin and therefore the backing construction is more distal from the skin than the primary drug containing layer. Even if the Examiner argues that the drug of Burkoth et al. is enclosed in microporous membrane, that microporous membrane is still not a backing. It may be that the microporous membrane acts as a bag and encloses a runny liquid drug. In that case, the device still requires a backing on top to protect the drug from leaking out on top. Thus, even if assuming the drug layer (2, 12, 22) of Burkoth et al. were enclosed by a microporus membrane, it is still covered by an *impermeable* backing layer (3, 15, 24), which is clearly shown and described by Burkoth et al. It is noted that the backing layers 3, 15, 24 are all stated by Burkoth et al. as being *impermeable*. Burkoth et al. refer to US4379454 regarding known skin-containing porous membrane. It is noted that in US4379454 the microporous layer 15 is between the reservoir and the adhesive (which faces the skin) and thus the microporous layer 15 is clearly not a backing layer. Withdrawal of the rejection is respectfully requested.

Further, in the present application the claims are now amended to state that the backing construction is embossed. It is noted that none of the cited reference has a backing that is embossed. To make a transdermal drug delivery device having an embossed multilaminate backing, there has to be an embossing process and lamination. As Applicant states in the specification, it is not an easy and obvious thing to provide embossed backing in a trandermal drug delivery device having a drug reservoir. If the backing is made of low melting material during lamination the backing will melt and render the backing transparent and defeat the effect of embossing. Adhesive can also intrude into the pores of a microporous backing. If the embossing is done after lamination, the embossing can cause problem in the drug reservoir or adhesive. Thus, there has been no teaching that an embossed backing be used in the prior art on a trandermal drug delivery device.

Withdrawal of the rejections is respectfully requested.

CONCLUSION

Applicant submits the pending claims are novel and nonobvious over prior art and comply with the requirements of 35 USC §102 and §112. The examination and passage to allowance of the pending claims are respectfully requested. An early Notice of Allowance is therefore earnestly solicited. Applicant invites the Examiner to contact the undersigned at (650) 564-7054 to clarify any unresolved issues raised by this response.

The Commissioner is hereby authorized to charge any additional fees associated with this paper or during the pendency of this application, or credit any overpayment, to Deposit Account No. 10-0750.

Respectfully submitted,

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